Guidelines for Reconsenting

(May 2023)

There are no regulatory requirements that address the issue or process for "re-consenting" subjects during a study. The regulations also do not:

- address all the circumstances that might require repeating or supplementing information previously provided as part of the informed consent process
- designate a threshold for the significance of the information that should be shared
- describe mechanisms for how new information should be provided

However, there are requirements related to promptly providing new information that becomes available during the conduct of a study that might affect the subject's decision to continue in the research. If the protocol design, risks, etc. have changed, it is necessary to ensure that the subjects still wish to participate in the research to ensure that their consent remains legally effective. This may be handled through re-consent, reaffirmation, or providing new information. Re-consent typically means re-signing the latest IRB approved informed consent document. Reaffirmation is confirmation or reassertion that the subject (or LAR) wishes to continue in the study is typically done verbally. When new information needs to be communicated to the research subject, this can be done via a consent addendum or information sheet. Which method is used should be least burdensome to subject and research team. Investigators and IRBs need to work together to determine the best approach since new information should not automatically result in signing a revised consent document.

Situations Which May Require Re-consent

The following are situations that may require re-consenting of research participants. They include:

- Identification of new research-related risks (e.g., Unanticipated problem that exposes subjects to new risks)
- Increase in the frequency or severity of previously described risks
- Decrease in expected benefits to participation
- Change to the research that results in increased burden or discomfort
- Availability of new alternative therapies
- Impact of participation on alternative therapies
- Significant changes in the research study including:
    - Change in investigational drug dosage or device application or in exposure to the drug/device
    - Change in duration of the subject in the trial or other changes likely to increase the burdens or discomforts of participation
    - Change in use of specimens obtained in the research

- Legal perspective including:
    - A subject did not sign the consent form
    - An inappropriate legal representative signed for the subject
    - Changes to medical treatment choices if research subject is injured due to the study
    - Change in the financial burden of participation (e.g., adding or removing compensation or renumeration for participants)
    - Changes in an investigator's conflict of interest (e.g., financial)

Consequences of Re-consenting to a Study

Re-consenting is not a harmless or trivial process. There are several things that need to be considered such as

- Increased subject anxiety
- Respecting subject's time
- Extra appointment for subject and research team
- Extra travel time/costs
- Investigator/research team time for reconsenting, locating subjects who may have changed addresses/phone numbers, and tracking
- Impact on recruiting goal
- Impact study statistical power

Re-consent versus subject notification

- If any of the following questions are answered yes, re-consenting is likely more appropriate:
    - Does the information include new or increased risks associated with the procedures or the intervention?
    - Does the information include changes to the study design, procedures, or intervention, that increase duration or other burdens to subjects?
    - Does the new information represent a change to the content in the signed consent form, and directly affect the rights or protections provided to subjects?
    - Does the subject need to agree to the information that is being shared in order to continue in the study?
- If any of the following questions are answered yes, notification is likely more appropriate:
    - Does the information represent a change of the PI or other staff, or their contact information, listed in the consent form?
    - Is a study ending earlier than planned (for reasons other than a change in risk to subjects)?
    - Is subjects' involvement in the research complete?

- Does the investigator wish to share preliminary findings of the research with subjects?

Mechanisms for Reconsent

- The following are options for reconsenting:
  - Repeat the informed consent process using a revised IRB approved long form consent with subject signature
  - Present new information using a consent addendum to the original consent document with subject signature or using an information sheet
  - The expectation is this would also involve a discussion with a subject.
  - Orally communicate the new information using a verbal script (communicated either face-to-face, over the telephone or via telehealth)
  - Use of a revised web-based consent form (usually applicable when the original IRB-approved consent process was web-based)
  - All should include documenting the re-consent process in CRIS.

Considerations for Notification Plan

All notification plans **must** be IRB approved prior to implementation – the exception being holding/stopping treatment to eliminate immediate risk to a subject. A subject should not be notified of a new risk and asked to reaffirm willingness to continue until the IRB has approved the plan. Consider the following when proposing how subjects will be notified:

- Determine what information needs to be communicated:
  - Change in risk (e.g., new or change in severity or frequency)
  - Change in level of discomfort or other inconvenience
  - Procedural change(s)
  - Change in remuneration or reimbursement
  - New alternative option available
- Determine who needs the information:
  - All subjects or subset of subjects
  - Subjects actively undergoing research intervention
  - Will the information affect subjects differently?
  - Examples:
    - If the information changes screening procedures, then subjects already receiving the study intervention won't be impacted by the change.
    - If the information changes drug dosing, then subjects who have completed dosing and are in follow-up won't be impacted by the change.
    - If information is related to a new risk (e.g., developing secondary cancer), then future, current and past subjects would be impacted by the new risk.

Note: While subjects who have completed dosing or are off study won't have their decision to participate or continue participation be affected, this may impact their future clinical care.

- Determine when to provide the subject with the new information or change:
    - Immediately
    - Before next visit
    - Before a specific study procedure
    - Timing may vary based on what the information is and which subjects (i.e., present, future, or past) may be impacted
    - Are subjects coming in for visits?
    - Do subjects have to travel to receive the new information or re-consent?
- Determine where and how to provide the information to the subject. Remember that when you are not re-consenting in person, verification of subject identity is required.
    - For new information or re-affirmation
        - Phone
        - Letter
        - Combination of phone and letter
    - For re-consenting
        - In-person visit may be best when complex information is being presented or need for physical demonstration or review of other documents
        - Phone/telehealth

Resources:

- Secretary's Advisory Committee on Human Research Protections (SACHRP), Attachment A -New Information Provided to Previously Enrolled Research Subjects (March 11, 2020), Recommendations to the HHS Secretary
    - Attachment A1 –Reconsent Appendix 1
    - Attachment A2 –Reconsent Appendix 2